Exhibit E

BARD
PERIPHERAL
VASCULAR

May 11, 2006

Food and Drug Administration
Center for Devices and Radiological Health
Medical Device Reporting
Attn: Jenne Liu, RN, MSN
P.O. Box 3002
Rockville, Maryland 20847-3002

RE: Report Number: 4900090000-2006-8002
Manufacturer's Report Number: 2020394-2006-00078

Per your request, Bard Peripheral Vascular (BPV), a division of C.R. Bard, Inc., is submitting a response to your request for additional information, dated April 3, 2006, concerning Report Number 4900090000-2006-8002. Please note that BPV has submitted a Manufacturer's MedWatch Report for this event, Manufacturer's Report Number 2020394-2006-00078, on February 24, 2006.

In an effort to provide clarification and ease of review, the FDA question/comment is noted in ***bold italics*** and is followed by BPV's response.

1. ***Any evaluation of other information used by your firm to determine whether the events described in the medical device report are or are not attributable to the device.***

   As reported in the Manufacturer's MedWatch report previously submitted: The Device History Records could not be reviewed, as the lot number was unknown. Neither the filter or the delivery system were returned for evaluation as they were discarded by the user. It is unknown if patient or procedural factors contributed to this event. Based on the information received, the results of the investigation are inconclusive.

2. ***All information, including any evaluation or analysis, from which your firm determined that the reported event has occurred, or is occurring, with lesser or greater frequency or severity than is stated in the labeling for the device or; if there is not any pertinent statement in the labeling, than is usual for the device. State the expected and observed frequency and severity of occurrence for the reported incident with this device.***

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The Information for Use for this device states: Complications may occur at any time during or after the procedure. Potential Complications include, but are not limited to, the following: Movement or migration of the filter is a known complication of vena cava filters. This may be caused by placement in IVCs with diameters exceeding the appropriate labeled dimensions specified in the IFU. Migration of filters to the heart or lungs have also been reported in association with improper deployment, deployment into clots, and/or dislodgement due to large clot burdens.

As defined in the Design Failure Modes and Effects Analysis (DFMEA) for this product, the expected frequency of occurrence for caudal migration is less than or equal to 0.05%. The observed frequency of occurrence is 0.129% (as of April 30th, 2006), of which no events have been associated with a patient death. As the actual rate of occurrence exceeds the expected rate, the level of risk for this specific failure mode was reassessed in the DFMEA. Upon secondary assessment, the overall risk level, which consists of occurrence, severity, and detection, remains below the risk threshold. The risk remains at an acceptable level per BPV's Risk Management System.

BPV established a low internal rate for migration in order to trigger formal monitoring of reported events that exceed the expected frequency and severity of occurrence. For the clinically relevant threshold rate (2%) for migration, one should consider the Society of Interventional Radiologists' (SIR) *Quality Improvement Guidelines*[1] (see **Attachment A**).

Table 1: G2 Filter Caudal Migration Rate vs. SIR Guidelines Event/Threshold Rates

Potential Complications	G2 Filter Rate Based on U.S. Sales	Complications/ Trackable Event Rates from SIR Guidelines[1] (all filters)*	Threshold % from SIR Guidelines (all filters)**
Movement/Migration (2 cm+)	0.129%	0-18%	2%

* Suggested threshold for individual practices for purposes of case review
** Migration/Movement includes filter embolization as described in the SIR Guidelines

Per **Table 1** above, BPV's overall migration rate is within the range of reported rates (0-18%) and below the threshold rates (2%), as described in the SIR *Quality Improvement Guidelines*.

[1] Grassi CJ, Swan TL, Cardella JF, et al. Quality Improvement Guidelines for Percutaneous Permanent Inferior Vena Cava Filter Placement for the Prevention of Pulmonary Embolism. J Vasc Interv Radiol 2003; 14:S271-S275.

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In conclusion, the G2 Filter migration rate is below the risk threshold per BPV's internal Risk Management System and is below the event rates and threshold reported in the SIR *Quality Improvement Guidelines*.

If you have any questions regarding this response, please do not hesitate to contact Cynthia Walcott by telephone at (480) 303-2747 or by fax at (480) 303-2774.

Kind Regards,

Cynthia Walcott

Cynthia Walcott, RN
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